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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF POLLUTION PREVENTION AND TOXICS

REGULATION OF A NEW CHEMICAL SUBSTANCE

PENDING DEVELOPMENT OF INFORMATION

In the matter of:	)	Premanufacture Notice Number:
	)	
	)	
	)	
	)	
	)	
[redacted]	)	P-12-0351
	)	
	)	
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Consent Order and Determinations Supporting Consent Order

[redacted]

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PREAMBLE

I. INTRODUCTION

Under the authority of § 5(e) of the Toxic Substances Control Act ("TSCA") (15 U.S.C. 2604(e)), the Environmental Protection Agency ("EPA" or "the Agency") issues the attached Order, regarding the premanufacture notice ("PMN") P-12-0351 for the chemical substance [redacted] ("the PMN substance) submitted by [redacted] ("the Company"), to take effect upon expiration of the PMN review period. The Company submitted the PMN to EPA pursuant to § 5(a)(1) of TSCA and 40 CFR Part 720.

Under § 15 of TSCA, it is unlawful for any person to fail or refuse to comply with any provision of § 5 or any order issued under § 5. Violators may be subject to various penalties and to both criminal and civil liability pursuant to § 16, and to specific enforcement and seizure pursuant to § 17. In addition, chemical substances subject to an Order issued under § 5 of TSCA, such as this one, are subject to the § 12(b) export notice requirement.

II. SUMMARY OF TERMS OF THE ORDER

The Consent Order for this PMN substance requires the Company to:

(a) record and report [redacted] starting raw material impurities;

(b) submit to EPA certain fate testing before manufacturing (defined by statute to include import) a total of [redacted] of the PMN substance;

(c) submit to EPA certain fate testing before manufacturing (defined by statute to include import) a total of [redacted] of the PMN substance;

(e) not exceed the maximum established levels of [redacted] impurities;

(f) not manufacture the PMN substance beyond an annual aggregate manufacture (defined by statute to include import)volume of [redacted];

(g) not distribute the PMN substance for use [redacted]; and,

(h) maintain certain records.

III. CONTENTS OF PMN

By signing this Order, the Company represents that it has carefully reviewed this document and agrees that all information herein that is claimed as confidential by the Company is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

Confidential Business Information Claims (Bracketed in the Preamble and Order): Company identity; chemical identity; impurities; production volume; specific use; operation descriptions, including exposure and release estimates; and physical/chemical properties.

Chemical Identity:

Specific: [redacted]

Generic: Siloxanes and Silicones, alkyl, alkyl propoxy ethyl, methyl octyl, alkyl polyfluorooctyl

Use:

Specific: [redacted]

Generic: Coating additive

Maximum 12-Month Production Volume: [redacted]

Test Data Submitted with PMN: none

IV. EPA'S ASSESSMENT OF EXPOSURE AND RISK

The following are EPA's predictions regarding the probable human and environmental toxicity, human exposure and environmental release of the PMN substance, based on the information currently available to the Agency.

Human Health Effects Summary:

EPA has concerns about potential fluorinated incineration or other decomposition products of the PMN substance. EPA expects that the PMN substance will degrade, based on data on [redacted] The PMN substance may degrade to [redacted].

Based on available information, EPA has determined that the PMN substance may have [redacted] impurities. The Company has agreed to routinely monitor the [redacted] levels in [redacted] for the following analytes: [redacted]. The Company will also annually monitor the [redacted] levels in [redacted] including establishing calibration curves where the LOQ desired is [redacted]. The Company shall report all monitoring results on an annual basis. The Company will work towards reducing the maximum amount of impurities [redacted].

EPA is concerned that perfluorinated products may be released to the environment from incomplete incineration of the PMN substance at low temperatures. EPA has preliminary evidence, including data on other [redacted], that suggests that, under some conditions, the PMN substance could degrade in the environment. EPA has concerns that these degradation products will persist in the environment, could bioaccumulate or biomagnify, and could be toxic ("PBT") to people, wild mammals, and birds based on data on analog chemicals, including PFOA. The potential perfluorinated degradants for these PMN substances include [redacted].

PFOA is expected to persist for years in the environment. Biodegradation and photolysis tests of analogous substances indicate little or no biodegradation or photolysis of perfluoroalkyl compounds. Bioaccumulation concerns are based on the measured presence of certain perfluoroalkyl compounds, including PFOA, in wildlife and in human blood samples. Toxicity studies on PFOA indicate developmental, reproductive and systemic toxicity in various species, as well as possible cancer concerns. These factors, taken together, raise concerns for potential adverse chronic effects in humans and wildlife. For additional information about PFOA, consult the EPA regulatory docket at OPPT-2003-0012. Additional information about PFOA, [redacted], and other perfluorinated substances may also be found in the *Administrative Record for PFOS, PFOA, and Telomers and Related Chemicals (AR-226). Administrative Record (AR-226)* is not currently available online, but copies can be requested on CD-ROM from the EPA Docket office by calling (202) 566-0280 or sending an email request to *oppt.ncic@epa.gov*.

Limited toxicological, ecological, and fate data now exist on [redacted] and some of the [redacted]-derived polymers and other substances; see the PMN docket for data for these specific PMNs. EPA previously received a pharmacokinetics study on [redacted] and, for comparison, perfluorobutane sulfonate ("PFBS") in the Cynomolgus Monkey. This study indicates that the

serum half-life of [redacted] is less than 24 hours in these monkeys. In comparison, the serum half-life of PFOA has been shown to be 20.9 days in female monkeys and 32.6 days in male monkeys. In addition, the serum half-life of PFOA in humans is approximately 3.8 years. Another pharmacokinetics study on [redacted] in rats showed a serum half-life of one hour or less. These data support the assessment of reduced bioaccumulation of [redacted] relative to PFOA.

In 2007, EPA received a 90-day study with a reproduction screen on [redacted] with dose levels of 0, 20, 100, and 500 mg/kg/day. EPA's review of this study concluded that a no-observed adverse effect level ("NOAEL") was not established in this study for systemic effects. Nasal tissue, liver, and thyroid effects were observed at 100 and 500 mg/kg/day; while body weight, red blood cell system, clotting and kidney effects were observed at 500 mg/kg/day. The EPA reviewer concluded that, although not clearly dose related, the elevation of two markers for liver toxicity across all treated groups of males in clinical chemistry and focal necrosis in the liver, across all treated groups of males, as well as in treated recovery males, and the absence of this result in the controls, leads to the conclusion that no NOAEL was achieved.

For the one-generation reproductive toxicity component of this study, the reproductive toxicity NOAEL is 500 mg/kg/day (the highest dose tested). The systemic toxicity NOAEL for P1 rats was 20 mg/kg/day based on decreased body weights/body weight gains at 100 and 500 mg/kg/day. The systemic toxicity for F1 adults is 100 mg/kg/day based on reduced body weights/body weight gains and reduced food consumption at 500 mg/kg/day. The developmental toxicity NOAEL for F1 pups was 100 mg/kg/day based on decrease pup weights at 500 mg/kg/day. The rats (P1 generation; 20/sex/group) were administered gavage doses of 0,

20, 100 or 500 mg/kg/day for 70 days pre-mating, and then mated for a maximum of 2 weeks to produce 1 litter. Dosing was continued during mating, gestation, and lactation.

In 2005, a Combined Repeated-Dose Toxicity Study with Reproduction/Developmental Screening Test, (OECD Test Guideline 422) in rats was conducted on [redacted]. The EPA review of these subchronic and reproductive data on [redacted] concluded that for [redacted], no reproductive effects were seen at 50, 150, and 450/300 mg/kg/day (450 was reduced to 300 in the study on day 4 because of toxicity) dose levels; however, systemic effects--primarily liver effects--were seen. EPA review places the NOAEL for [redacted] at 50 mg/kg/day.

In 2006, another 90-day oral repeated dose toxicity study (OECD Test Guideline 408) was submitted with dose levels of 0 (vehicle control), 10, 50, or 200 mg/kg/day, based on the previous Combined Study (OECD Test Guideline 422). EPA review sets the Lowest-Observed Effect Level ("LOEL") or LOAEL at 10 mg/kg/day, based on the lower body weight gains in all treated groups of males. There was treatment-related toxicity in the liver and the red blood cell system (anemia) in males, as well as increased peroxisomal beta oxidation activity at 200 mg/kg/day. Hepatotoxicity and peroxisomal beta oxidation activity have been observed in studies on PFOA.

The significance of the finding of a benign brain tumor (astrocytoma) in one male rat in the high dose group is not clear. The tumor is not the type normally associated with PFOA-type compounds, is not rare, and may be incidental. Abnormal histopathology observations in the testes of 2 males and epididymides of 1 male, at the 200 mg/kg/day dose level, are a sign of male reproductive toxicity. Further testing should investigate male reproductive effects. From this study, the potential for immunotoxic effects is low in contrast to some studies showing immunotoxic effects from PFOA. Any investigation of immunotoxic effects should await the

corroborative studies now being conducted by EPA, Office of Research and Development. There were no clinical signs of neurotoxicity and there were no treatment-related effects in the functional observation battery or motor behavior.

Two other 90-day studies have been submitted on [redacted]. EPA review of those studies concluded that there were effects at higher doses. For one study, there were blood and liver effects at the highest dose. In the other study, there were effects seen at the two higher doses. In the reproductive component of one of the studies, there were some effects at the highest dose (500 mg/kg/day). These two studies had comparable dose levels.

A one-generation reproduction/developmental toxicity study in mice on the ammonium salt of [redacted] (OECD 421, modified) was submitted to the Agency. In this study, pregnant mice were administered the test substance via gavage during gestation days 6-18. The NOAEL for maternal toxicity was 175 mg/kg/day (the highest dose tested). Signs of developmental toxicity were observed at 175 mg/kg/day on the postnatal day 1 and consisted of increases in the number of stillborn pups and pup deaths, reductions in the average pup body weight per litter, and a pup with lenticular opacity. The NOAEL for developmental toxicity is 35 mg/kg/day.

A Chronic Toxicity, Carcinogenicity study was submitted in 2011. Doses were 2.5, 15, and 100 mg/kg/day for males and 5, 30, and 200 mg/kg/day for females. EPA review determined that no chronic toxicity or carcinogenicity effects were seen in the two lower doses. Due to limitations in the study, no determination could be made for the highest doses.

These and other data indicate a different and less toxic profile for [redacted], (a presumed environmental degradant of the PMN substance), than for PFOA. However, based on: (1) the persistence of [redacted]; (2) potential intermediate fate products; and, (3) the possibility or likelihood that this substance may be used as a major substitute for some uses of PFOA, EPA

believes that more information is needed on the toxicity of [redacted] and possibly other environmental degradants and the fate, and physical/chemical properties of [redacted]-derived or related polymers in the environment.

EPA also believes that additional reproductive and long-term toxicological studies on [redacted] in animals are warranted. Further, EPA expects that a modified reproductive test (OECD Test Guideline 421, modified) and a two year Carcinogenicity/Chronic Toxicity test in rats (OECD Test Guideline 453) will also be conducted by other companies. The modifications for the reproductive test include: (1) increase the parental sample size to 20, (2) the duration of the study should be extended to until the pups have reached sexual maturation, (3) parental males should be dosed for 10 weeks prior to mating, (4) dosing of the parental animals should be continued through lactation and then the pups should be directly dosed until they reach sexual maturation, (5) pup body weight should be recorded on lactation days 0, 4, 7, 14, and 21 and then at weekly intervals, (6) litter size can be standardized to 4 pups/litter on lactation day 4 (optional), (7) at weaning one pup/sex/litter can be randomly selected to follow until sexual maturation, and (8) the time of sexual maturation should be recorded (i.e. vaginal opening and preputial separation). An avian reproduction test (OECD 206) has also been conducted. In addition, comparative data, especially on the pharmacokinetics of [redacted] and other perfluorinated substances will be developed by testing of the National Toxicology Program (NTP) in the so called Perfluoro Class Study.

Mammalian toxicity and aquatic studies were submitted for an analog to the PMN substance. EPA believes that these are acceptable analogs for mammalian toxicity; however, EPA questions the appropriateness of the analog for ecotoxicity due to differences in solubility. EPA believes that additional characterization in mammalian studies of the PMN substance would

be valuable, but based on the above information will not require this additional data be submitted.

Environmental Effects Summary:

EPA expects the PMN substance or the degradants to be highly persistent. In addition, there is high concern for possible environmental effects from the potential persistent degradation product [redacted]. As stated previously, the analog PFOA is persistent in the environment; has a long bioretention time in various species; has been detected in a number of species of wildlife, including marine mammals, and is considered toxic to mammalian and other species. The toxicological properties and presence of PFOA in the environment continue to be investigated. While EPA has limited acute ecotoxicological effects data on [redacted] in fish, daphnia, and algae, additional chronic data on [redacted] is desired. EPA anticipates these tests are being conducted by other companies.

EPA received the Avian Reproduction Test on [redacted] in late 2011. The test was conducted according to OPPTS 850.2300, OECD 206 and FIFRA Subdivision E Section 71-4 guidelines and under GLP conditions. Results showed no adverse effects in adult northern bobwhite quail exposed to 1,000 ppm, 5,000 ppm or 10,000 ppm for body weight, feed consumption, or reproductive parameters. In addition, no effects were observed in the offspring of the exposed adults. The NOEC is 10,000 ppm or 964 mg/kglday. Although the original test recommendations included analysis for [redacted] of the livers of the adult birds as well as the blood and livers of the offspring for the presence of [redacted], the fact that the analysis was not performed will not alter the validation of the study considering the lack of effects seen in adult

tissue at necropsy and the lack of signs of toxicity in both the adult and offspring as a whole. In summary, the NOEC remains 10,000 ppm or 964 mg/kg/day.

Thermal and simulated incineration testing exists on some related polymers. This testing indicates that incomplete incineration products are formed at lower incineration temperatures. Modified Zahn-Wellens and Semi-Continuous Activated Sludge ("SCAS") biodegradation tests have been conducted on some related polymers. EPA has determined that some related polymers degrade, while another did not show signs of degradation during the time frame of the test. EPA has received and reviewed test data showing that certain polymers with perfluoroalkyl substituents degrade to form perfluoroalkyl containing intermediates and perfluoroalkyl containing organic acids. EPA expects that the PMN substance will degrade in this way.

Exposure and Environmental Release Summary:

Manufacturing - P-12-0351 is expected to be [redacted]. Occupational exposures are [redacted]. Releases of the PMN substance to the environment are [redacted].

Use - [redacted] is expected to occur at [redacted] Occupational exposures are [redacted] Releases of the PMN substance to the environment are [redacted].

V. EPA'S CONCLUSIONS OF LAW

The following findings constitute the basis of the Consent Order:

(a) EPA is unable to determine the potential for human health and environmental effects from exposure of humans and aquatic organisms to the PMN substance. EPA therefore concludes, pursuant to § 5(e)(1)(A)(i) of TSCA, that the information available to the Agency is insufficient to permit a reasoned evaluation of the human health and environmental effects of the PMN substance.

(b) In light of the potential risk of human health and environmental effects posed by the uncontrolled manufacture (defined by statute to include import), processing, distribution in commerce, use, and disposal of the PMN substance, EPA has concluded, pursuant to § 5(e)(1)(A)(ii)(I) of TSCA, that uncontrolled manufacture (defined by statute to include import), processing, distribution in commerce, use, and disposal of the PMN substance may present an unreasonable risk of injury to human health and the environment.

(c) In light of the estimated production volume of, and human exposure to the PMN substance, EPA has further concluded, pursuant to § 5(e)(1)(A)(ii)(II) of TSCA, that the PMN substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities, and there may be significant (or substantial) human exposure to the substance.

VI. INFORMATION REQUIRED TO EVALUATE HUMAN HEALTH AND ENVIRONMENTAL EFFECTS

Triggered Testing. The Order prohibits the Company from exceeding a specified production volume unless the Company submits the information described in the Testing section of this Order in accordance with the conditions specified in the Testing section.

Pended Testing. The following additional information would be required to evaluate the following effects which may be caused by the PMN substance:

Study	Test Guideline
Modified Semi-Continuous Activated Sludge (SCAS) with analysis of degradation products	OPPTS 835.5045/OECD 302A
Anaerobic biodegradability of organic compounds in digested sludge	OECD 311
Phototransformation of Chemicals on Soil Surfaces – 2 soils	Draft OECD (Jan. 2002)
Aerobic and Anaerobic Transformation in Aquatic Sediment Systems	OECD 308
Acute inhalation toxicity test	OPPTS 870.1300
Avian Reproduction Test (*Anas platyrhynhcos*)	OPPTS 850.2300
Fish Short-term Reproduction Assay (*Oryzias latipes*)	OPPTS 890.1350

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

[redacted]

CONSENT ORDER

I. SCOPE OF APPLICABILITY AND EXEMPTIONS

(a) Scope. The requirements of this Order apply to all commercial manufacturing, processing, distribution in commerce, use and disposal of the chemical substance [redacted] (P-12-0351) ("the PMN substance") in the United States by [redacted] ("the Company"), except to the extent that those activities are exempted by paragraph (b).

(b) Exemptions. Manufacturing, processing, distribution in commerce, use and disposal of the PMN substance is exempt from the requirements of this Order (except the requirements in the Recordkeeping and Successor Liability Upon Transfer Of Consent Order sections) only to the extent that (1) these activities are conducted in full compliance with all applicable requirements of the following exemptions, and (2) such compliance is documented by appropriate recordkeeping as required in the Recordkeeping section of this Order.

(1) Export. Until the Company begins commercial manufacture of the PMN substance for

use in the United States, the requirements of this Order do not apply to manufacture, processing or distribution in commerce of the PMN substance solely for export in accordance with TSCA §§12(a) and 12(b), 40 CFR 720.3(s) and 40 CFR Part 707. However, once the Company begins to manufacture the PMN substance for use in the United States, no further activity by the Company involving the PMN substance is exempt as "solely for export" even if some amount of the PMN substance is later exported. At that point, the requirements of this Order apply to all activities associated with the PMN substance while in the territory of the United States. Prior to leaving U.S. territory, even those quantities or batches of the PMN substance that are destined for export are subject to terms of the Order, and count towards any production volume test triggers in the Testing section of this Order.

(2) Research & Development ("R&D"). The requirements of this Order do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance in small quantities solely for research and development in accordance with TSCA §5(h)(3), 40 CFR 720.3(cc), and 40 CFR 720.36. The requirements of this Order also do not apply to manufacturing, processing, distribution in commerce, use and disposal of the PMN substance when manufactured solely for non-commercial research and development per TSCA §5(i) and 40 CFR 720.30(i).

(3) Byproducts. The requirements of this Order do not apply to the PMN substance when it is produced, without separate commercial intent, only as a "byproduct" as defined at 40 CFR 720.3(d) and in compliance with 40 CFR 720.30(g).

(4) No Separate Commercial Purpose. The requirements of this Order do not apply to the PMN substance when manufactured, pursuant to any of the exemptions in 40 CFR 720.30(h), with no commercial purpose separate from the substance, mixture, or article of which it is a part.

(5) Imported Articles. The requirements of this Order do not apply to the PMN substance

when imported as part of an "article" as defined at 40 CFR 720.3(c) and in compliance with 40 CFR 720.22(b)(1).

(c) Automatic Sunset. If the Company has obtained for the PMN substance a Test Market Exemption ("TME") under TSCA §5(h)(1) and 40 CFR 720.38 or a Low Volume Exemption ("LVE") or Low Release and Exposure Exemption ("LoREX") under TSCA §5(h)(4) and 40 CFR 723.50(c)(1) and (2) respectively, any such exemption is automatically rendered null and void as of the effective date of this Consent Order..

II. TERMS OF MANUFACTURE, IMPORT, PROCESSING, DISTRIBUTION IN COMMERCE, USE, AND DISPOSAL PENDING SUBMISSION AND EVALUATION OF INFORMATION

PROHIBITION

The Company is prohibited from manufacturing (defined by statute to include import), processing, distributing in commerce, using, or disposing of the PMN substance in the United States, for any nonexempt commercial purpose, pending the development of information necessary for a reasoned evaluation of the human health and environmental effects of the substance, and the completion of EPA's review of, and regulatory action based on, that information, except in accordance with the conditions described in this Order.

CHEMICAL SYNTHESIS AND COMPOSITION

(a) Restriction. The Company shall not manufacture the PMN substance unless testing of the [redacted] starting raw material, as supplied by the raw material supplier in a Certificate of Analysis,

meets the established purity levels as specified in Table 1 and Table 2 of this Order. If, within one year before the date of manufacture of the PMN substance, a product that contained [redacted] products was processed or manufactured in the equipment at the facility where the PMN substance is to be made, the Company shall test the Initially Isolated Formulations of the PMN substance for the analytes specified in Table 3 of this Order to confirm that cross-contamination from the manufacture of the products with [redacted] has not occurred. Testing shall be conducted upon initial commencement of manufacture and at least annually thereafter, until one year after the date of the last manufacture or processing of a product that contains [redacted] products at the facility. No testing of initially isolated formulations of the PMN substance will be required if [redacted] have not been previously manufactured or processed in the facility. The Company shall record the levels of impurities [redacted] associated with the PMN substance manufactured by the Company, as specified below. The Company shall record analytes present in the [redacted] at each manufacturing facility using the raw material (as shown in Table 1). Further, the Company will also annually record the analyte [redacted] present in the [redacted] starting raw material (as shown in Table 2). The Company shall make its reasonable best effort to minimize these impurities. If any new manufacturing facilities are added, or the manufacturing process is significantly altered, then the PMN substance must be tested at commencement of these actions and annually thereafter.

(b) Reporting. The Company shall test representative samples of the Initially Isolated Formulation of the PMN substance manufactured (defined by statute to include import) by the Company to determine compliance with the requirements in paragraph (a). The Company shall

test the Initially Isolated Formulation of the PMN substance at each manufacturing facility both (1) at the initial commencement of non-exempt manufacture of the PMN substance at that facility, and (2) at least annually thereafter during every year in which the PMN substance are manufactured (defined by statute to include import) at that facility. The Initially Isolated Formulation of the PMN substance does not have to be tested as noted above if within one year before the date of manufacture of the PMN substance a product that contained [redacted] products was not processed or manufactured in the equipment at the facility where the PMN substance are to be made. If any new facility of manufacture is added, or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered, then the Initially Isolated Formulation of the PMN substance must be tested at commencement of these actions and annually thereafter. If the PMN substance is imported, the Company shall obtain from the foreign manufacturer written documentation to certify that representative samples of the imported form of the PMN substance have been tested, consistent with the requirements of this paragraph (b) and determined to comply with the requirements of paragraph (a).

The Company shall report the above testing to EPA at initial commencement of manufacture (defined by statute to include import) and again if any new manufacturing facility is added or if the process of manufacture of the PMN substance or any intermediate thereof is significantly altered. The Company shall continue to report these impurity levels to EPA annually. This is consistent with the current annual reporting cycle [redacted]. In addition to the reporting for the Initially Isolated Formulations of the PMN substance, the Company shall, for the [redacted] starting raw material, annually report (1) the average values and the range of values, including outlying data, for the routine testing for the analytes specified in Table 1 and (2) the results of the annual testing for the

analyte specified in Table 2. For purposes of Table 1 and Table 2 testing, the Company may rely on third party supplier Certificates of Analysis provided with each shipment of [redacted] to the Company, provided EPA has approved the test protocol(s) used by that third party.

TABLE 1: Chemicals to be Routinely Tested in Starting Raw Material

Analyte	CAS Number	Limit in [redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

TABLE 2: Chemicals to be Annually Tested in Starting Raw Material

Analyte	CAS Number	Limit in [redacted]
[redacted]	[redacted]	[redacted]

TABLE 3: Chemicals to be Tested in the Initially Isolated Formulations of the PMN Substance

Analyte	CAS Number	Limit in Initially Isolated Formulations
[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]

TESTING

(a) Section 8(e) Reporting. Reports of information on the PMN substance which reasonably supports the conclusion that the PMN substance presents a substantial risk of injury to health or the environment and which is required to be reported under TSCA section 8(e) shall reference the appropriate PMN identification number for the substance and contain a statement that the substance is subject to this Consent Order. Additional information regarding section 8(e) reporting requirements can be found at *www.epa.gov/oppt/tsca8e*.

(b) Notice of Study Scheduling. The Company shall notify, in writing, the EPA Monitoring Assistance and Media Programs Division (2227A), Office of Enforcement and Compliance Assurance, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460, of the following information within 10 days of scheduling any study required to be performed pursuant to this Order, or within 15 days after the effective date of this Order, whichever is later:

(1) The date when the study is scheduled to commence;

(2) The name and address of the laboratory which will conduct the study;

(3) The name and telephone number of a person at the Company or the laboratory whom EPA may contact regarding the study; and,

(4) The appropriate PMN identification number for the substance and a statement that the substance is subject to this Consent Order.

(c) Good Laboratory Practice Standards and Test Protocols. Each study performed to address the risks identified in this Order must be conducted according to TSCA Good Laboratory Practice

Standards at 40 CFR Part 792 and using methodologies generally accepted in the relevant scientific community at the time the study is initiated. Before starting to conduct any study that will use a modified version of a published test guideline, the Company must submit written test protocols to EPA for review (submission of written test protocols is optional for tests that are to be conducted using unmodified published test guidelines). Protocols must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. EPA will respond to the Company within 4 weeks of receiving the written protocols. EPA review of a test protocol does not mean pre-acceptance of test results.

(d) Triggered Testing Requirements. The Company is prohibited from manufacturing (defined by statute to include import) the PMN substance beyond the aggregate manufacture (defined by statute to include import) volumes ("the production limits"), unless the Company conducts the following studies on the PMN substance and submits all final reports and underlying data in accordance with the conditions specified in this Testing section.

Production Limit	Study	Test Guideline
Tier 1 [redacted]	Direct Photolysis	OPPTS 835.2210
Tier 2 [redacted]	Indirect Photolysis Screening Test	OPPTS 835.5270

(e) Test Reports. The Company shall: (1) conduct each study in good faith, with due care, and in a scientifically valid manner; (2) promptly furnish to EPA the results of any interim phase of each study; and (3) submit the final report of each study (with an additional sanitized copy, if confidential business information is involved) and all underlying data ("the report and data") to EPA prior to exceeding the applicable production limit. The final report and data must be submitted as a support document for the PMN, using the procedures set out in 40 CFR 720.40. The final report shall contain the contents specified in 40 CFR 792.185. Underlying data shall be submitted to EPA in accordance with the applicable "Reporting," "Data and Reporting," and "Test Report" subparagraphs in the applicable test guidelines. However, for purposes of this Consent Order, the word "should" in those subparagraphs shall be interpreted to mean "shall" to make clear that the submission of such information is mandatory. EPA will require the submission of raw data such as slides and laboratory notebooks only if EPA finds, on the basis of professional judgment, that an adequate evaluation of the study cannot take place in the absence of these items.

(f) Testing Waivers. The Company is not required to conduct a study specified in paragraph (d) of this Testing section if notified in writing by EPA that it is unnecessary to conduct that study.

(g) Equivocal Data. If EPA finds that the data generated by a study are scientifically equivocal, the Company may continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit. To seek relief from any other restrictions of this Order, the Company may make a second attempt to obtain unequivocal data by reconducting the study under the conditions specified in paragraphs (b), (c), and (e) (except that the study may be submitted after reaching the applicable production limit). The testing requirements may be

modified, as necessary to permit a reasoned evaluation of the risks presented by the PMN substance, only by mutual consent of EPA and the Company.

(h) EPA Determination of Invalid Data.

(1) Except as described in subparagraph (h)(2), if, within 6 weeks of EPA's receipt of a test report and data, the Company receives written notice that EPA finds that the data generated by a study are scientifically invalid, the Company is prohibited from further manufacture (defined by statute to include import) of the PMN substance beyond the applicable production limit.

(2) The Company may continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit only if so notified, in writing, by EPA in response to the Company's compliance with either of the following subparagraphs (h)(2)(i) or (h)(2)(ii).

(i) If there is sufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may reconduct the study. If there is insufficient time to reconduct the study in compliance with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (h)(1). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data.

(ii) The Company may, within 4 weeks of receiving from EPA the notice described in subparagraph (h)(1), submit to EPA a written report refuting EPA's finding. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report.

(i) Company Determination of Invalid Data.

(1) Except as described in subparagraph (i)(2), if the Company becomes aware that circumstances clearly beyond the control of the Company or laboratory will prevent, or have prevented, development of scientifically valid data under the conditions specified in paragraphs (c) and (e), the Company remains prohibited from further manufacture (defined by statute to include import) of the PMN substance beyond the applicable production limit.

(2) The Company may submit to EPA, within 2 weeks of first becoming aware of such circumstances, a written statement explaining why circumstances clearly beyond the control of the Company or laboratory will cause or have caused development of scientifically invalid data. EPA will notify the Company of its response, in writing, within 4 weeks of receiving the Company's report. EPA's written response may either:

(i) allow the Company to continue to manufacture (defined by statute to include import) the PMN substance beyond the applicable production limit, or

(ii) require the Company to continue to conduct, or to reconduct, the study in compliance with paragraphs (b), (c), and (e), if there is sufficient time to conduct or reconduct the study and submit the report and data to EPA before exceeding the production limit specified in paragraph (d). If there is insufficient time for the Company to comply with paragraphs (b), (c), and (e) before exceeding the production limit specified in paragraph (d), the Company may exceed the production limit, but must otherwise comply with paragraphs (b), (c), and (e), and shall submit the report and data to EPA within a reasonable period of time, all as specified by EPA in the notice described in subparagraph (i)(2). EPA will respond to the Company, in writing, within 6 weeks of receiving the Company's report and data, as to whether the Company may continue to manufacture (defined by statute to include import) beyond the applicable production limit.

(j) Unreasonable Risk.

(1) EPA may notify the Company in writing that EPA finds that the data generated by a study are scientifically valid and unequivocal and indicate that, despite the terms of this Order, the PMN substance will or may present an unreasonable risk of injury to human health or the environment. EPA's notice may specify that the Company undertake certain actions concerning further testing, manufacture (defined by statute to include import), processing, distribution, use and/or disposal of the PMN substance to mitigate exposures to or to better characterize the risks presented by the PMN substance. Within 2 weeks from receipt of such a notice, the Company must cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the PMN substance, unless either:

(1) within 2 weeks from receipt of the EPA notice, the Company complies with such requirements as the notice specifies; or

(2) within 4 weeks from receipt of the EPA notice, the Company submits to EPA a written report refuting EPA's finding and/or the appropriateness of any additional requirements imposed by EPA. The Company may continue to manufacture (defined by statute to include import), process, distribute, use and dispose of the PMN substance in accordance with the terms of this Order pending EPA's response to the Company's written report. EPA will respond to the Company, in writing, within 4 weeks of receiving the Company's report. Within 2 weeks of receipt of EPA's written response, the Company shall comply with any requirements imposed by EPA's response or cease all manufacture (defined by statute to include import), processing, distribution, use and disposal of the PMN substance.

(k) Other Requirements. Regardless of the satisfaction of any other conditions in this Testing section, the Company must continue to obey all the terms of this Consent Order until otherwise notified in writing by EPA. The Company may, based upon submitted test data or other relevant information, petition EPA to modify or revoke provisions of this Consent Order pursuant to Part VI. of this Consent Order.

RISK NOTIFICATION

(a) If as a result of the test data required under the terms of this Order, the Company becomes aware that the PMN substance may present a risk of injury to health or the environment (or is so notified by EPA), the Company must incorporate this new information, and any information on methods for protecting against such risk, into a Material Safety Data Sheet ("MSDS"), as described in 40 CFR section 721.72(c), within 90 days from the time the Company becomes aware of the new information. If the PMN substance are not being manufactured (defined by statute to include import), processed, or used in the Company's workplace, the Company must add the new information to an MSDS before the PMN substance are reintroduced into the workplace.

(b) The Company must ensure that persons who will receive the PMN substance from the Company, or who have received the PMN substance from the Company within 5 years from the date the Company becomes aware of the new information described in paragraph (a) of this section, are provided an MSDS containing the information required under paragraph (a) within 90 days from the time the Company becomes aware of the new information.

MANUFACTURING

(a)(1) Prohibition. The Company shall not cause, encourage, or suggest the manufacture (defined by statute to include import) of the PMN substance by any other person.

(2) Sunset Following SNUR. Subparagraph (a)(1) shall expire 75 days after promulgation of a final significant new use rule ("SNUR") governing the PMN substance under section 5(a)(2) of TSCA unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (a)(1) shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed.

(3) Notice of SNUR. When EPA promulgates a final SNUR for the PMN substance and subparagraph (a)(1) expires in accordance with subparagraph (a)(2), the Company shall notify each person whom it causes, encourages or suggests to manufacture (defined by statute to include import) the PMN substance of the existence of the SNUR.

(b) The Company shall not manufacture the PMN substance beyond an annual manufacture (defined by statute to include import) volume of [redacted].

USE

(a) The Company shall not use the PMN substance [redacted].

DISTRIBUTION

(a) Export Notice Requirement. No later than the date of distribution, the Company shall notify in

writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(b) Distribution Requirements. The Company shall distribute the PMN substance outside the Company, other than for disposal, only to a person who has agreed in writing prior to the date of distribution, to:

(1) Notify in writing any person to whom it distributes the PMN substance that, due to the issuance of this Consent Order under section 5(e) of TSCA, the PMN substance is subject to the export notification requirements of TSCA section 12(b) and 40 CFR Part 707 Subpart D. Such notice shall contain, in the form in which it appears in this Consent Order, the following information: (1) the PMN number, and (2) either (A) the specific chemical identity of the PMN substance, or (B) if the specific chemical identity is confidential, the generic chemical identity.

(2) Not further distribute the PMN substance to any other person, other than for disposal.

(3) Not use the PMN substance in consumer spray applications including but not limited to those that generate a vapor, mist, or aerosol.

(c) Temporary Transport and Storage. Notwithstanding paragraph (b), the Company may distribute the PMN substance outside the Company for temporary transport and storage in sealed containers provided the following three conditions are met:

(1) Subsequent to any such exempt temporary transport or storage of sealed containers, the PMN substance may be distributed only to the Company or a person who has given the Company the written agreement required by paragraph (b).

(2) Any human exposure or environmental release resulting from opening the sealed containers and removing or washing out the PMN substance may occur only while the PMN substance is in the possession and control of the Company or a person who has given the Company the written agreement required by paragraph (b).

(d) Recipient Non-Compliance. If, at any time after commencing distribution in commerce of the PMN substance, the Company obtains knowledge that a recipient of the substance has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section or, after subparagraph (b)(2) expires in accordance with subparagraph (e)(1), has engaged in a significant new use of the PMN substance (as defined in 40 CFR Part 721, Subpart E) without submitting a significant new use notice to EPA, the Company shall cease supplying the substance to that recipient, unless the Company is able to document each of the following:

(1) That the Company has, within 5 working days, notified the recipient in writing that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA.

(2) That, within 15 working days of notifying the recipient of the noncompliance, the Company received from the recipient, in writing, a statement of assurance that the recipient is aware of the terms of paragraph (b) of this Distribution section and will comply with those terms, or is aware of the terms of the significant new use rule for the PMN substance and will not engage

in a significant new use without submitting a significant new use notice to EPA.

(3) If, after receiving a statement of assurance from a recipient under subparagraph (d)(2) of this Distribution section, the Company obtains knowledge that the recipient has failed to comply with any of the conditions specified in paragraph (b) of this Distribution section, or has engaged in a significant new use of the PMN substance without submitting a significant new use notice to EPA, the Company shall cease supplying the PMN substance to that recipient, shall notify EPA of the failure to comply, and shall resume supplying the PMN substance to that recipient only upon written notification from the Agency.

(e) Sunset Following SNUR. (1) Subparagraph (b)(2) of this Distribution section shall expire 75 days after promulgation of a final SNUR for the PMN substance under section 5(a)(2) of TSCA, unless the Company is notified on or before that day of an action in a Federal Court seeking judicial review of the SNUR. If the Company is so notified, subparagraph (b)(2) of this Distribution section shall not expire until EPA notifies the Company in writing that all Federal Court actions involving the SNUR have been resolved and the validity of the SNUR affirmed. (2) When EPA promulgates a final SNUR for the PMN substance and subparagraph (b)(2) of this Distribution section expires in accordance with subparagraph (e)(1), the Company shall notify each person to whom it distributes the PMN substance of the existence of the SNUR. Such notification must be in writing and must specifically include all limitations contained in the SNUR which are defined as significant new uses, and which would invoke significant new use notification to EPA for the PMN substance. Such notice must also reference the publication of the SNUR for this PMN substance in either the Federal Register or the Code of Federal Regulations. After promulgation of a SNUR and expiration of subparagraph (b)(2), such notice may substitute for the

written agreement required in the introductory clause of paragraph (b); so that, if the Company provides such notice to the persons to whom it distributes the PMN substance, then the Company is not required to obtain from such persons the written agreement specified in paragraph (b).

III. RECORDKEEPING

(a) Records. The Company shall maintain the following records until 5 years after the date they are created and shall make them available for inspection and copying by EPA in accordance with section 11 of TSCA:

(1) Exemptions. Records documenting that the PMN substance did in fact qualify for any one or more of the exemptions described in Section I, Paragraph (b) of this Order. Such records must satisfy all the statutory and regulatory recordkeeping requirements applicable to the exemption being claimed by the Company. Any amounts or batches of the PMN substance eligible for the export only exemption in Section I, Paragraph (b)(1) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, copies of the export label and export notice to EPA, required by TSCA sections 12(a)(1)(B) and 12(b), respectively. Any amounts or batches of the PMN substance eligible for the research and development exemption in Section I, Paragraph (b)(2) of this Order are exempt from all the requirements in this Recordkeeping section, if the Company maintains, for 5 years from the date of their creation, the records required by 40 CFR 720.78(b). For any amounts or batches of the PMN substance claimed to be eligible for any other exemption described in Section I, Paragraph (b) of this Order, the Company shall keep records demonstrating qualification for that exemption as well as the records specified in paragraphs (2) and (3) below, but is exempt from the other recordkeeping requirements in this Recordkeeping section;

(2) Records documenting the manufacture (defined by statute to include import) volume of the PMN substance and the corresponding dates of manufacture (defined by statute to include import);

(3) Records documenting the names and addresses (including shipment destination address, if different) of all persons outside the site of manufacture (defined by statute to include import) to whom the Company directly sells or transfers the PMN substance, the date of each sale or transfer, and the quantity of the substance sold or transferred on such date;

(4) Records documenting the address of all sites of manufacture (defined by statute to include import), processing, and use to which the Company sells or transfers the PMN substance;

(5) Records documenting compliance with any applicable manufacturing and use in the Chemical Composition, Manufacturing, Use, Risk Notification, and Distribution sections of this Order,

(6) Copies of any Transfer Documents and notices required by the Successor Liability section of this Order, if applicable; and,

(7) The Company shall keep a copy of this Order at each of its sites where the PMN substance is manufactured (defined by statute to include import).

(b) Applicability. The provisions of this Recordkeeping Section are applicable only to activities of the Company and its Contract Manufacturer, if applicable, and not to activities of the Company's customers.

(c) OMB Control Number. Under the Paperwork Reduction Act and its regulations at 5 CFR Part 1320, particularly 5 CFR 1320.5(b), the Company is not required to respond to this "collection of

information" unless this Order displays a currently valid control number from the Office of Management and Budget ("OMB"), and EPA so informs the Company. The "collection of information" required in this TSCA §5(e) Consent Order has been approved under currently valid **OMB Control Number 2070-0012.**

IV. REQUESTS FOR PRE-INSPECTION INFORMATION

(a) EPA's Request for Information. Pursuant to section 11 of TSCA and 40 CFR 720.122, EPA may occasionally conduct on-site compliance inspections of Company facilities and conveyances associated with the PMN substance. To facilitate such inspections, EPA personnel may contact the Company in advance to request information pertinent to the scheduling and conduct of such inspections. Such requests may be written or oral. The types of information that EPA may request include, but are not limited to, the following:

(1) Expected dates and times when the PMN substance will be in production within the subsequent 12 months;

(2) Current workshift schedules for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(3) Current job titles or categories for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(4) Existing exposure monitoring data for workers who are involved in activities associated with the PMN substance and may reasonably be exposed to the PMN substance;

(5) Records required by the Recordkeeping section of this Order; and/or,

(6) Any other information reasonably related to determining compliance with this Order or conducting an inspection for that purpose.

(b) Company's Response. The Company shall respond to such requests within a reasonable period of time, but in no event later than 30 days after receiving EPA's request. When requested in writing by EPA, the Company's response shall be in writing. To the extent the information is known to or reasonably ascertainable by the Company at the time of the request, the Company's response shall demonstrate a good faith effort to provide reasonably accurate and detailed answers to all of EPA's requests.

(c) Confidential Business Information. Any Confidential Business Information ("CBI") that the Company submits to EPA pursuant to paragraph (b) shall be protected in accordance with §14 of TSCA and 40 CFR Part 2.

V. SUCCESSOR LIABILITY UPON TRANSFER OF CONSENT ORDER

(a) Scope. This section sets forth the procedures by which the Company's rights and obligations under this Order may be transferred when the Company transfers its interests in the PMN substance, including the right to manufacture the PMN substance, to another person outside the Company (the "Successor in Interest").

(b) Relation of Transfer Date to Notice of Commencement ("NOC").

(1) Before NOC. If the transfer from the Company to the Successor in Interest is effective before EPA receives a notice of commencement of manufacture (defined by statute to include import) ("NOC") for the PMN substance from the Company pursuant to 40 CFR 720.102, the Successor in Interest must submit a new PMN to EPA and comply fully with Section 5(a)(1) of

TSCA and 40 CFR part 720 before commencing manufacture (defined by statute to include import) of the PMN substance.

(2) After NOC. If the transfer from the Company to the Successor in Interest is effective after EPA receives a NOC, the Successor in Interest shall comply with the terms of this Order and shall not be required to submit a new PMN to EPA.

(c) Definitions. The following definitions apply to this Successor Liability section of the Order:

(1) "Successor in Interest" means a person outside the Company who has acquired the Company's full interest in the rights to manufacture the PMN substance, including all ownership rights and legal liabilities, through a transfer document signed by the Company, as transferor, and the Successor in Interest, as transferee. The term excludes persons who acquire less than the full interest of the Company in the PMN substance, such as a licensee who has acquired a limited license to the patent or manufacturing rights associated with the PMN substance. A Successor in Interest must be incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3) and 40 CFR 720.3(z).

(2) "Transfer Document" means the legal instrument(s) used to convey the interests in the PMN substance, including the right to manufacture the PMN substance, from the Company to the Successor in Interest.

(d) Notices.

(1) Notice to Successor in Interest. On or before the effective date of the transfer, the Company shall provide to the Successor in Interest, by registered mail, a copy of the Consent

Order and the "Notice of Transfer" document which is incorporated by reference as Attachment B to this Order.

(2) Notice to EPA. Within 10 business days of the effective date of the transfer, the Company shall, by registered mail, submit the fully executed Notice of Transfer document to: U.S. Environmental Protection Agency, New Chemicals Management Branch (7405), 1200 Pennsylvania Avenue, N.W., Washington, D.C. 20460.

(3) Transfer Document. Copies of the Transfer Document must be maintained by the Successor in Interest at its principal place of business, and at all sites where the PMN substance is manufactured (defined by statute to include import). Copies of the Transfer Document must also be made available for inspection pursuant to Section 11 of TSCA, must state the effective date of transfer, and must contain provisions which expressly transfer liability for the PMN substance under the terms of this Order from the Company to the Successor in Interest.

(e) Liability.

(1) The Company shall be liable for compliance with the requirements of this Order until the effective date of the transfer described above.

(2) The Successor in Interest shall be liable for compliance with the requirements of this Order effective as of the date of transfer.

(3) Nothing in this section shall be construed to prohibit the Agency from taking enforcement action against the Company after the effective date of the transfer for actions taken, or omissions made, during the time in which the Company manufactured, processed, used, distributed in commerce, or disposed of the PMN substance pursuant to the terms of this Consent Order.

(f) Obligations to Submit Test Data under Consent Order. If paragraph (d) of the Testing section of this Consent Order requires the Company to submit test data to EPA at specified production volumes ("test triggers"), the aggregate volumes of the PMN substance manufactured (defined by statute to include import) by the Company up to the date of transfer shall count towards the test triggers applicable to the Successor in Interest.

VI. MODIFICATION AND REVOCATION OF CONSENT ORDER

The Company may petition EPA at any time, based upon new information on the human health or environmental effects of, or human exposure to or environmental release of, the PMN substance, to modify or revoke substantive provisions of this Order. The exposures and risks identified by EPA during its review of the PMN substance and the information EPA determined to be necessary to evaluate those exposures and risks are described in the preamble to this Order. However, in determining whether to amend or revoke this Order, EPA will consider all relevant information available at the time the Agency makes that determination, including, where appropriate, any reassessment of the test data or other information that supports the findings in this Order, an examination of new test data or other information or analysis, and any other relevant information. In the event that the Company would like to petition the Agency to modify or revoke the restriction contained under the Use section of this Order, the Agency expects an acute inhalation toxicity test (OPPTS 870.1300) on the PMN substance to accompany such petition. In the event that the Company would like to petition the Agency to modify or revoke the restriction contained under the Manufacturing section of this Order, the Agency expects an modified semi-continuous activated sludge (SCAS) study with analysis of degradation products (OPPTS

835.5045/OECD 302A) and an anaerobic biodegradability of organic compounds in digested sludge study (OECD 311) on the PMN substance to accompany such petition.

EPA will issue a modification or revocation if EPA determines that the activities proposed therein will not present an unreasonable risk of injury to health or the environment and will not result in significant or substantial human exposure or substantial environmental release in the absence of data sufficient to permit a reasoned evaluation of the health or environmental effects of the PMN substance.

In addition, the Company may petition EPA at any time to make other modifications to the language of this Order. EPA will issue such a modification if EPA determines that the modification is useful, appropriate, and consistent with the structure and intent of this Order as issued.

VII. EFFECT OF CONSENT ORDER

(a) Waiver. By consenting to the entry of this Order, the Company waives its rights to file objections to this Order pursuant to section 5(e)(1)(C) of TSCA, to receive service of this Order no later than 45 days before the end of the review period pursuant to section 5(e)(1)(B) of TSCA, and to challenge the validity of this Order in any subsequent action. Consenting to the entry of this Order, and agreeing to be bound by its terms, do not constitute an admission by the Company as to the facts or conclusions underlying the Agency's determinations in this proceeding. This waiver does not affect any other rights that the Company may have under TSCA.

(b) CBI Brackets. By signing this Order, the Company represents that it has carefully reviewed this document and hereby agrees that all information herein that is claimed as confidential by the Company (per section 14 of TSCA, 40 CFR Part 720 Subpart E, and 40 CFR Part 2) is correctly identified within brackets and that any information that is not bracketed is not claimed as confidential. To make this document available for public viewing, EPA will remove only the information contained within the brackets.

20 Feb 2015
Date

Maria J. Doa, Ph.D., Director
Chemical Control Division
Office of Pollution Prevention and Toxics

5 MAR 2015
Date

Name: Konrad Wernthaler
Title: Vice President
Company: BASF Corp.

ATTACHMENT A

DEFINITIONS

[Note: The attached Order may not contain some of the terms defined below.]

"Chemical name" means the scientific designation of a chemical substance in accordance with the nomenclature system developed by the Chemical Abstracts Service's rules of nomenclature, or a name which will clearly identify a chemical substance for the purpose of conducting a hazard evaluation.

"Chemical protective clothing" means items of clothing that provide a protective barrier to prevent dermal contact with chemical substances of concern. Examples can include, but are not limited to: full body protective clothing, boots, coveralls, gloves, jackets, and pants.

"Company" means the person or persons subject to this Order.

"Commercial use" means the use of a chemical substance or any mixture containing the chemical substance in a commercial enterprise providing saleable goods or a service to consumers (e.g., a commercial dry cleaning establishment or painting contractor).

"Common name" means any designation or identification such as code name, code number, trade name, brand name, or generic chemical name used to identify a chemical substance other than by its chemical name.

"Consumer" means a private individual who uses a chemical substance or any product containing the chemical substance in or around a permanent or temporary household or residence, during recreation, or for any personal use or enjoyment.

"Consumer product" means a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation.

"Container" means any bag, barrel, bottle, box, can, cylinder, drum, reaction vessel, storage tank, or the like that contains a hazardous chemical. For purposes of this section, pipes or piping systems, and engines, fuel tanks, or other operating systems in a vehicle, are not considered to be containers.

"Contract Manufacturer" means a person, outside the Company, who is authorized to manufacture and import the PMN substance under the conditions specified in Part II. of this Consent Order and in the Consent Order for Contract Manufacturer.

"Identity" means any chemical or common name used to identify a chemical substance or a mixture containing that substance.

"Immediate use." A chemical substance is for the "immediate use" of a person if it is under the control of, and used only by, the person who transferred it from a labeled container and will only be used by that person within the work shift in which it is transferred from the labeled container.

"Impervious." Chemical protective clothing is "impervious" to a chemical substance if the substance causes no chemical or mechanical degradation, permeation, or penetration of the chemical protective clothing under the conditions of, and the duration of, exposure.

"Manufacturing stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of manufacture, including the cleaning of equipment.

"MSDS" means material safety data sheet, the written listing of data for the chemical substance.

"NIOSH" means the National Institute for Occupational Safety and Health of the U.S. Department of Health and Human Services.

"Non-enclosed process" means any equipment system (such as an open-top reactor, storage tank, or mixing vessel) in which a chemical substance is manufactured, processed, or otherwise used where significant direct contact of the bulk chemical substance and the workplace air may occur.

"Non-industrial use" means use other than at a facility where chemical substances or mixtures are manufactured, imported, or processed.

"PMN substance" means the chemical substance described in the Premanufacture notice submitted by the Company relevant to this Order.

"Personal protective equipment" means any chemical protective clothing or device placed on the body to prevent contact with, and exposure to, an identified chemical substance or substances in the work area. Examples include, but are not limited to, chemical protective clothing, aprons, hoods, chemical goggles, face splash shields, or equivalent eye protection, and various types of respirators. Barrier creams are not included in this definition.

"Process stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of processing, including the cleaning of equipment.

"Scientifically invalid" means any significant departure from the EPA-reviewed protocol or the Good Laboratory Practice Standards at 40 CFR Part 792 without prior or subsequent Agency review that prevents a reasoned evaluation of the health or environmental effects of the PMN substance.

"Scientifically equivocal data" means data which, although developed in apparent conformity with the Good Laboratory Practice Standards and EPA-reviewed protocols, are inconclusive, internally inconsistent, or otherwise insufficient to permit a reasoned evaluation of the potential risk of injury to human health or the environment of the PMN substance.

"Sealed container" means a closed container that is physically and chemically suitable for long-term containment of the PMN substance, and from which there will be no human exposure to, nor environmental release of, the PMN substance during transport and storage.

"Use stream" means all reasonably anticipated transfer, flow, or disposal of a chemical substance, regardless of physical state or concentration, through all intended operations of industrial, commercial, or consumer use.

"Waters of the United States" has the meaning set forth in 40 CFR 122.2.

"Work area" means a room or defined space in a workplace where the PMN substance is manufactured, processed, or used and where employees are present.

"Workplace" means an establishment at one geographic location containing one or more work areas.

ATTACHMENT B

NOTICE OF TRANSFER
OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

_____ _____
Company (Transferor) PMN Number

1. Transfer of Manufacture Rights. Effective on _____, the Company did sell or otherwise transfer to _____, ("Successor in Interest") the rights and liabilities associated with manufacture of the above-referenced chemical substance, which was the subject of a premanufacture notice ("PMN") and is governed by a Consent Order issued by the U.S. Environmental Protection Agency ("EPA") under the authority of §5(e) of the Toxic Substances Control Act ("TSCA," 15 U.S.C. §2604(e)).

2. Assumption of Liability. The Successor in Interest hereby certifies that, as of the effective date of transfer, all actions or omissions governed by the applicable Consent Order limiting manufacture, processing, use, distribution in commerce and disposal of the PMN substance, shall be the responsibility of the Successor in Interest. Successor in Interest also certifies that it is incorporated, licensed, or doing business in the United States in accordance with 40 CFR 720.22(a)(3).

3. Confidential Business Information. The Successor in Interest hereby:

___ reasserts,

___ relinquishes, or

___ modifies

all Confidential Business Information ("CBI") claims made by the Company, pursuant to Section 14 of TSCA and 40 CFR part 2, for the PMN substance(s). Where "reasserts" or "relinquishes" is indicated, that designation shall be deemed to apply to all such claims. Where "modifies" is indicated, such modification shall be explained in detail in an attachment to this Notice of Transfer. Information which has been previously disclosed to the public (e.g., a chemical identity that was not claimed as CBI by the original submitter) would not subsequently be eligible for confidential treatment under this Notice of Transfer.

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER

(continued)

Company (Transferor)	PMN Number
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Successor in Interest	
Signature of Authorized Official	Date
Printed Name of Authorized Official	
Title of Authorized Official	
Address	
City, State, Zip Code	

NOTICE OF TRANSFER OF
TOXIC SUBSTANCES CONTROL ACT
SECTION 5(e) CONSENT ORDER
(continued)

_____

Successor's Technical Contact

_____

Address

_____

City, State, Zip Code

_____

Phone